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| APPLICATION NO. | FILING DA | ATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------|-----------------------|-----------|----------------------|-------------------------|------------------|
| 08/989,881 | 08/989,881 12/12/1997 | | JEN SHEEN | 08472/716002 | 9398 |
| 7 | 590 03 | 3/28/2002 | | | |
| KAREN L EI | | EXAMINER | | | |
| CLARK & ELI | STREET | | COLLINS, CYNTHIA E | | |
| BOSTON, MA 02110 | | | • | ART UNIT | PAPER NUMBER |
| | | | | 1638 | Jo |
| | | | | DATE MAILED: 03/28/2002 | Œ. |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Amplication | No. | 1 4 10 4/-> | | | | | |
|---|--|----------------------|------------|--------------|--|--|--|--|--|
| Office Action Summary | | Application | No. | Applicant(s) | | | | | |
| | | 08/989,881 | · | SHEEN, JEN | | | | | |
| | | Examiner | | Art Unit | | | | | |
| | | Cynthia Co | | 1638 | | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | | | | |
| 1)🖾 | Responsive to communication(s) filed on 12 h | <u> March 2001</u> . | | | | | | | |
| 2a)⊠ | This action is FINAL . 2b) Th | is action is n | on-final. | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | | | |
| Disposition of Claims | | | | | | | | | |
| 4) Claim(s) 1-7,24-26,36-46,49 and 50 is/are pending in the application. | | | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | | |
| 6)⊠ | Claim(s) <u>1-7, 24-26, 36-46, 49 and 50</u> is/are re | ejected. | | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | | | |
| 8) | Claim(s) are subject to restriction and/o | r election red | quirement. | | | | | | |
| Application | on Papers | | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. | | | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | | | |
| a) All b) Some * c) None of: | | | | | | | | | |
| 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. | | | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | | | |
| a) The translation of the foreign language provisional application has been received. 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | | | | |
| Attachment(s) | | | | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4) Interview Summary (PTO-413) Paper No(s) 5) Notice of Informal Patent Application (PTO-152) 6) Other: | | | | | | | | | |

DETAILED ACTION

The Amendment filed February 12, 2001, paper no.19, has been entered.

Claims 1, 24 and 36 are newly amended.

Claims 49-50 are newly added.

Claims 1-7, 24-26, 36-46 and 49-50 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 18, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 1-7, 24-26, 36-39 and 41-46 remain rejected under 35 U.S.C. 112, first paragraph, for written description, for the reasons of record set forth in the office actions mailed October 14, 1999 and August 8, 2000.

Applicant's arguments filed February 8, 2001, have been fully considered but they are not persuasive.

Applicant argues that Saijo et al. (Exhibits A and B) provide evidence of the existence of CDPK genes that confer tolerance to multiple environmental stresses, that representative examples are not required by statute and are not an end in themselves, and that the specification must covey clearly to those skilled in the art that the inventor has invented the specific subject matter claimed (response, p.7-8).

The Saijo et al. references (Exhibits A and B) were published subsequent to the filing of the instant application, and therefore cannot be used to describe the claimed invention. The

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specification must describe the claimed invention at the time of filing. Additionally, unless Applicant describes the structural and physical features characteristic of nucleic acids encoding calcium-dependent protein kinases that function to protect plants against environmental stress, the specification cannot convey clearly to those skilled in the art that the inventor has invented the specific subject matter claimed. Nucleic acids encoding calcium-dependent protein kinases that function to protect plants against environmental stress cannot be described solely by the function of the encoded protein. An adequate description of such a genus is achieved by the recitation of a representative number of sequences that fall within the scope of that genus, or the recitation of structural features constituting a substantial portion of the genus that are common to the members of the genus. Applicant has not described the structural and physical features characteristic of nucleic acids encoding calcium-dependent protein kinases that function to protect plants against environmental stress, Applicant has described a single nucleic acid sequence encoding a calcium-dependent protein kinase that function to protect plants against drought stress, SEQ ID NO:1.

Claims 1-7, 24-26 and 36-46 remain rejected, and newly added claims 49-50 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing transgenic plants that are drought tolerant as a result of the overexpression of a transgene encoding the PK domain of AtCDPK1, does not reasonably provide enablement for other methods for producing transgenic plants that are tolerant to environmental stress as a result of the overexpression of other transgenes encoding other CDPK polypeptides that include a PK domain, for the reasons of record set forth in the office actions mailed October 14, 1999 and August 8, 2000.

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Applicant's arguments filed February 8, 2001, have been fully considered but they are not persuasive.

Applicant argues that the specification provides clear guidance, using specific examples, for identifying and isolating DNA sequences encoding CDPK polypeptides having PK domains from a variety of sources, that the cloning of two maize CDPKs by Saijo et al. (Exhibit A) leaves no reason to believe that Applicant's specification does not enable the isolation and identification of additional CDPK genes from any plant without undue experimentation, that determining whether a gene encoding a CDPK is easily accomplished by overexpressing the gene in a transgenic plant, and that the overexpression of a single CDPK conferring both cold and salt/drought tolerance on rice plants taught by Saijo et al. (Exhibit B) confirms the specification's teaching that the expression of CDPK genes encoding PK domain promotes protection against a number of environmental stresses (response, p.4-6).

Although the specification provides guidance for identifying and isolating DNA sequences encoding CDPK polypeptides having PK domains, such guidance is not sufficient to enable the full scope of the invention. The specification lacks guidance for identifying and isolating DNA sequences encoding CDPK polypeptides having PK domains that confer stress tolerance in transgenic plants. Although Dr. Sheen's declaration discloses a method for producing transgenic plants that are drought tolerant as a result of the overexpression of the nucleotide sequence encoding AtCDPK1 when operatively linked to the 35S promoter, the specification does not disclose, and the prior art does not teach, other CDPKs that confer stress tolerance in plants when overexpressed. The specification does not disclose, and the prior art does not teach, the structural elements of CDPKs that are essential for conferring stress tolerance in transgenic plants. The specification does not provide those skilled in the art with guidance as

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to which amino acids could or could not be changed without altering the ability of a CDPK to confer stress tolerance in a transgenic plant. In the absence of such guidance, it would require undue experimentation for one of skill in the art to determine whether a particular CDPK would or would not confer stress tolerance in a transgenic plant. Accordingly, the publication of the Saijo et al. references (Exhibits A and B) subsequent to the filing of the instant application does not remedy the failure of Applicant's specification to provide sufficient guidance to enable one skilled in the art to practice the claimed invention in its full scope.

The rejection of claims 36 and 40 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "substantially", is withdrawn in light of the definition of substantially provided on pages 7-8 of the specification.

Claim Rejections - 35 USC § 102

Claims 36-46 remain rejected under 35 U.S.C. 102(b) as being anticipated by Urao et al. (Mol. Gen. Genet. 1994, Vol. 244, pages 331-340), for the reasons of record set forth in the office actions mailed October 14, 1999 and August 8, 2000.

Applicant's arguments filed February 8, 2001, have been fully considered but they are not persuasive.

Applicant argues that since Urao et al. discloses full length cDNA molecules encoding full length CDPK polypeptides, Urao et al. does not disclose a DNA molecule encoding a PK domain consisting essentially of itself (response, p.8-9).

The Examiner maintains that the disclosure of full length cDNA molecules encoding full length CDPK polypeptides by Urao et al. does disclose a DNA molecule encoding a PK domain consisting essentially of itself. The reference teaches the nucleotide and deduced amino acid sequences of ATDPK1 and ATDPK2 isolated from *Arabidopsis*, which are substantially

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identical to the nucleotide sequence of SEQ ID NO:1 (Figure 3A,B, page 334). The sequences taught by Urao et al. inherently include a DNA molecule that encodes a polypeptide consisting essentially of a PK domain.

Accordingly, Applicant's argument is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

March 25, 2002

AMY J. NELSON, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600